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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/726,202
Filing Date: December 01, 2003
Appellant(s): BATCH, RICHARD M.

John A. Hankins
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 21 August 2008 appealing from the Office action mailed 21 November 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

20020099273	Bocionek	07-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-6, 8-17 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bocionek et al. (U.S. Pub. No. 2002/0099273). Bocionek et al. (hereinafter Bocionek) disclose a medical information system which retains and processes information from various sources for use in clinical care delivery. Regarding claims 1, 3, 8-9 and 22, Bocionek teaches a system for analyzing medical treatment data associated with medical treatment from a plurality of patients to determine a treatment guideline based on treatment administered to a plurality of patients, and for updating at least one medical device (infusion pump **85**) with the guideline ([0020], [0027], [0030]). Database **75** stores medical treatment data associated with medical treatments delivered to a plurality of patients; the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter such as vital signs, drug interactions and patient organ images ([0018], [0020], [0024], [0028], [0029]). A processor connected to the database is configured to compile from the medical

treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the values and determine a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022]. Decision functions **15** and **17** automatically supply a medical device such as an infusion pump with an optimized drug dosage [0027]. With further reference to claim 3, database **77** stores preestablished medical treatment guidelines [0020].

Regarding claims 2 and 4, a statistical distribution is provided by the analysis of the complied treatment parameters as evidenced by alarm function **27**, serving as a function of optimized thresholds. Decision support functions **15** and **17** determine new or improved treatment solutions, thus adjusting acceptable values for the selected treatment parameter in the preestablished guidelines [0027]. A message based on a particular analysis may be displaced to a user on a monitor or an interface display [0035], thus generating a report of the analysis or comparison in accordance with claims 5 and 6.

With respect to claim 10, the medical treatment data may include patient physiological data such as vital signs. Decision support functions derive conclusions based on the vital signs and available patient data and parameters to optimize settings and thresholds ([0026]-[0027]).

Regarding claim 11, Bocionek teaches a plurality of medication administration devices **81-87** for multiple patients, each associated with data acquired from a patient including patient identification, medication and operating parameters. A central processor **19**, **21** is configured to receive medical treatment data from the administration

devices and a database **77** operatively connected to the processor stores preestablished medical treatment guidelines representing acceptable values for the medical administration device operating parameters. Interface **90** interconnects medical devices within a patient's room to the central processor. The processor is further configured to compile a plurality of parameter values associated with a selected device operating parameter, analyzed the values and determine a medical treatment guideline based on the analysis representing acceptable values ([0016], [0017], [0028]).

Referring to claim 12, Bocionek teaches a method of communicating medical treatment data associated with medical treatments delivered to a plurality of patients, the treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each parameter; compiling from the treatment data a plurality of parameter values associated with a selected parameter; analyzing the complied treatment parameter values, determining an optimal treatment guideline based on the analysis and providing the optimized guideline to an infusion pump from a remote location ([0018], [0020], [0024], [0027]-[0030]). Regarding claim 13, a statistical distribution is provided by the analysis of the complied treatment parameters as evidenced by alarm function **27**, serving as a function of optimized thresholds.

With reference to claim 14, database **77** stores preestablished medical treatment guidelines [0020]. Decision functions **15** and **17** compare compiled treatment parameter values such as from patient monitoring devices to the acceptable values for a treatment parameter retrieved from preestablished medical treatment guidelines in

database **77** [0024]. The decision functions determine new and improved treatment solutions which are substituted for the existing solutions in database **77**, thus creating an updated medical treatment guideline [0026], in accordance with claim 15. A message based on a particular analysis may be displaced to a user on a monitor or an interface display [0035], thus generating a report of the analysis or comparison in accordance with claims 16 and 17.

Regarding claims 19-21, database **77** is dynamically updated to incorporate improved treatments and their associated medical outcome results [0020]. A processor connected to the database compiles from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyzes the values and determines a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022].

With respect to claim 23, Bocionek teaches a system for analyzing medical treatment data associated with medical treatment from a plurality of patients to determine a treatment guideline based on treatment administered to a plurality of patients, and for updating at least one medical device (infusion pump **85**) with the guideline ([0020], [0027], [0030]). Database **75** stores medical treatment data associated with medical treatments delivered to a plurality of patients; the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter such as vital signs, drug interactions and patient organ images ([0018], [0020], [0024], [0028], [0029]). A processor connected to the database is configured to compile from

the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the values and determine a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022]. Decision functions **15** and **17** automatically supply a medical device such as an infusion pump with an optimized drug dosage [0027]. Alarm function **29** generates an alarm based on vital signs collected from patient monitoring units. Decision support functions derive conclusions based on medical data and patient vital signs and parameters and optimize the alarm function settings and thresholds [0026].

(10) Response to Argument

Regarding the rejection of claims 1, 11 and 12 under 35 U.S.C. 102(b) as being anticipated by Bocionek et al. (U.S. Pub. No. 2002/0099273), Appellant asserts that the control of the medical device, as taught by Bocionek, is not the same as providing a medical device with a revised treatment guideline. In other words, Appellant asserts that the medical device of Bocionek is receiving an instruction rather than a guideline. However, this argument is not persuasive. No special technical definition has been set forth in the specification which would distinguish the claimed "guideline" over the instructions of Bocionek. Furthermore, the "optimal drug dosage" to be applied by the infusion pump [0027] is considered to be a treatment guideline since it is "a guide to a future course of action," as established by dictionary.com. "Optimal drug dosage" is considered a guideline because it has been found to be the best or most satisfactory treatment, or course of action. It is also noted that the language of claim 1 does not

provide for the administration of an amount of a treatment substance by the medical device, or even delivery of a treatment substance. Appellant contends that it is commonly understood that guidelines are considered to be limits within which different courses may be followed. It is respectfully submitted that the Appellant here implies that a guideline defines a particular range. However, the definition of a guideline (as provided above) does not pose such limitations to the term. An indication of a future course of action, a policy, principle or rule does not necessarily include a range. The "optimal drug dosage" is also considered to be "revised treatment guidelines" because the optimal dosage is based on the available vital signs and medical data [0027]. Additionally, the decision functions derive conclusions based on these available medical data and vital signs and subsequently optimize settings and thresholds [0026], further supporting revised treatment guidelines.

Appellant asserts that the modules and function in Bocionek update patient records, rather than medical devices, and the updating does not involve treatment guidelines. As mentioned previously, the treatment guideline does not necessarily need to involve a range, but could be something such as a vital sign which a caregiver could use as a guide when administering treatment. However, the "optimal drug dosage" to be applied to the infusion pump based on medical data and vital signs is considered to be an updated treatment guideline [0027]. On another note, the "at least one medical device" may be a patient monitor at a bedside location [0019]. The display may suggest an alternative prescription or warning of a proposed treatment or medication [0035]

based on improved thresholds and treatment plans concluded from patient parameters ([0024] and [0028]).

Appellant also asserts that the alarm of Bocionek is only an alarm of vital signals, and not medical treatment guideline violations. However, this argument is not persuasive. In response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The alarm, as taught by Bocionek, is fully capable of generating an alert based on treatment parameters as it is functional in the teachings to be signaled based on any parameter relative to a patient's data which falls outside a specific, pre-established threshold [0026]. Furthermore, Bocionek teaches that the alarm function **29** generates an alarm based on individual, composite or weighted composite vital signs from units **81-87** which constitute "medical devices." Appellant further asserts that a "library of appropriate parameters" has not been addressed. As to the library, to further clarify, it is noted that it is interpreted as the vital signs recorded by the medical device. In view of the foregoing, the rejection of claims 1, 11 and 12 under 35 U.S.C. 102(b) as being anticipated by Bocionek et al. (U.S. Pub. No. 2002/0099273) has been maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/C. D. H./
Christine D. Hopkins
Examiner
Art Unit 3735

Conferees:

/Charles A. Marmor, II/
Supervisory Patent Examiner, Art Unit 3735

/Janet C. Baxter/
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